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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,317	03/26/2004	Andy H. Levine	2814.2007-001	8007

21005 7590 04/30/2008

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
SU, SUSAN SHAN	

ART UNIT	PAPER NUMBER
4193	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,317	LEVINE ET AL.	
	Examiner	Art Unit	
	SUSAN SU	4193	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *22 January 2008, 01 June 2006, 31 March 2006, 17 February 2006, 26 November 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Art Unit: 4193

DETAILED ACTION

Claim Objections

1. Claims 5-9, 19, 20-23 are objected to because of the following informalities: in Claims 5-7, 19, 20, & 23, there is lack of antecedent basis for "flexible sleeve" or "sleeve." The examiner believes that these claims are dependent on Claim 3 instead of Claim 1. Claims 8-9 and 21-22 are dependent on the objected Claims 7 & 21 and are therefore also objected to. Appropriate correction is required.

2. Claim 10 is objected to because of the following informalities:

In Claim 10: lack of antecedent basis for "sleeve material;" in addition, "about 0.2" is unclear. There is no mention of a sleeve in Claim 1. The examiner believes that the instant claim is dependent on Claim 3 and should be reworded to say "The gastrointestinal implant device of Claim 3, wherein the sleeve comprises a material having a coefficient of friction of less than 0.2." The examination is carried out based on the examiner's interpretation of the claim as reworded above. Appropriate correction is required.

3. Claims 23-25 are objected to because of the following informalities: in Claim 23, the word "securedly" is misspelled. It should be changed to –securely--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

> only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 5-7, & 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Kagan et al. (U.S. PGPub 2005/0096750).

With regard to Claim 1, Kagan et al. (hereinafter Kagan) teach a gastrointestinal implant device (Fig. 34) comprising an elongated tube (520) defining a central lumen, the tube being open at both ends (see figure and [0327]), and adapted to extend into the duodenum (see figure); and an anchor (528) coupling the proximal end (524) of the tube in alignment with the hepatopancreatic ampulla, and the tube passes digestive enzymes (last sentence [0325]) from the hepatopancreatic ampulla into a distal portion of the gastrointestinal tract.

With regard to Claim 3, as applied to Claim 1, Kagan also teaches that the tube comprises a flexible sleeve ([0332]).

With regard to Claim 5, as applied to Claim 3, Kagan also teaches that the flexible sleeve is formed of expanded polytetrafluoroethylene ([0333] where fluoropolyment as defined in [0254] includes expanded PTFE).

With regard to Claim 6, as applied to Claim 3, Kagan also teaches that the flexible sleeve is formed of polyethylene ([0333]).

With regard to Claim 7, as applied to Claim 3, Kagan also teaches that the flexible sleeve comprises a coating ([0333]).

With regard to Claims 15-17, as applied to Claim 1, Kagan also teaches that the anchor is collapsible, formed of shape memory material, and comprises a nickel-titanium alloy (last sentence of [0340]).

With regard to Claim 18, as applied to Claim 1, Kagan also teaches that the anchor comprises a stent ([0338]).

Art Unit: 4193

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 2, 4, 8-9, 20, & 27-38 are rejected under 35 U.S.C. 103(a) as being obvious over Kagan.

With regard to Claim 2, as applied to Claim 1, Kagan teaches the limitations of this claim except that the anchor is positioned within the hepatopancreatic ampulla. However, it is common practice in the gastrointestinal implant device art to anchor a tube at the exit of a body lumen (such as where the esophagus leads to the stomach or where the stomach connects to the duodenum). Hence the examiner asserts that it takes only routine skill for one of ordinary skill in the art to place the anchor at the hepatopancreatic ampulla. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kagan with an anchor at the hepatopancreatic ampulla for the purpose of efficiently collecting bile and pancreatic fluids with a shorter tube (the tube does not need to extend into the common bile duct, and shorter tube uses less material).

With regard to Claim 4, as applied to Claim 1, Kagan teaches the limitations of this claim except that the distal portion of the gastrointestinal tract is the distal jejunum. However, since it is common medical knowledge in the art that the jejunum is where most of the nutrient absorption takes place through the intestinal villi, it is desirable to lessen the exposure of digestive enzymes to food in this segment of the intestine in order to minimize absorption (also disclosed in [0032]). Therefore it is asserted by the examiner that it takes routine skill for one of ordinary skill in this art to modify the length of the tube so that it correlates with the amount of absorption that the doctor prescribes for the patient. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kagan so that the tube passes digestive enzymes into the distal jejunum.

With regard to Claims 8 & 9, as applied to Claim 7, Kagan teaches the limitations of this claim except that the coating is a polyurethane- or silicone-based coating. However, Kagan discloses that the tube can be coated with a low friction material ([0333]), and it is common knowledge that polyurethane and silicone are biocompatible low friction materials widely used for coating of medical devices. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kagan so that the coating is polyurethane- or silicone-based for the purpose of providing a biocompatible surface to minimize irritation in the intestine.

With regard to Claim 20, as applied to Claim 3, Kagan teaches the limitations of this claim (that the anchor comprises barbs extending from the exterior surface of the anchor, the barbs configured for securing the proximal portion of the sleeve, disclosed in [0338]) except that the securing is in the hepatopancreatic ampulla. However, as explained in Claim 2, it is common practice in the gastrointestinal implant device art to anchor a tube at the exit of a body lumen. Therefore it would have been obvious to one of ordinary skill in the art at the time of the

invention to modify Kagan so that the barbs secures the sleeve in the hepatopancreatic ampulla for the purpose of collecting bile and pancreatic fluids with a shorter tube.

With regard to Claims 27 & 38, Kagan teaches all the limitations of the claims except that the tube is anchored in the hepatopancreatic ampulla. As explained above in Claim 2, merely changing the anchor location does not render the device or its methods of use patentably distinct over prior art. In addition, Kagan teaches those digestive enzymes are deposited into the distal intestine via peristalsis ([0332]).

With regard to Claims 28 & 35, as previously discussed in Claim 2 concerning the anchor location, Kagan further teaches in the title that the device (and therefore the method of its use where the steps are dependent on the features of the device) is for weight loss. Since the Applicant admitted that the prevalence of Type-2 diabetes is strongly positively correlated with obesity, in that obesity often leads to signs of Type-2 diabetes (it is also common medical knowledge). Hence the treatment of obesity as claimed by Kagan will also treat Type-2 diabetes.

With regard to Claims 29-34 & 36-37, as applied to Claims 28 & 35 above, Kagan also teaches all the limitations of the instant claims as previously discussed in Claims 27, 3, 5, 6, 20, 4, 3, and 35, respectively.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being obvious over Kagan in view of Sahatjian et al. (U.S. Patent 5,135,516). As applied to Claim 3, Kagan substantially teaches the limitations of this claim except that the sleeve comprises a material having a coefficient of friction of less than 0.2. Sahatjian et al. (hereinafter Sahatjian) teaches a medical device that is made of polyethylene with a coefficient of friction of less than 0.2 (Col. 3 lines 15-19). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kagan with Sahatjian for the purpose of minimizing injury to the organs of the patient.

7. Claims 11-14 & 21-22 are rejected under 35 U.S.C. 103(a) as being obvious over Kagan in view of Dua et al. (U.S. PGPub 2002/0032487).

With regard to Claims 11-14, as applied to Claim 1, Kagan substantially teaches the limitations of the claims except that the anchor is cylindrical, defining a lumen, and preferably having an external diameter selected to provide an interference fit with the hepatopancreatic ampulla, that it preferably has an external diameter between 5 and 10millimeters, or that it has a length between 1 and 5 centimeters. Dua teaches an anchor that is cylindrical (see Fig. 1), defining a lumen, and has an external diameter selected to provide an interference fit with the lumen that it is used in. Since the hepatopancreatic ampulla is about 4mm in diameter and increases with age, and also having a length of about 15mm, it takes routine skills in the art to modify the size of the anchor so that the device would fit snugly in place. It takes only routine skills in the art to modify the size of the anchor. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kagan with Dua for the purpose of keeping the device implanted within the hepatopancreatic ampulla by providing the device with sufficient surface area and radial force onto the wall of the hepatopancreatic ampulla.

With regard to Claims 21 & 22, as applied to Claim 20 above, Kagan teaches the limitations of the claims except that the barbs are configured to penetrate bodily tissues or that they are substantially bi-directional. In the second embodiment disclosed by Dua, the barbs (65, Fig. 13) are configured to penetrate bodily tissue (when there is a force pulling on the anchor towards the lumen of the duodenum) and that they are substantially bi-directional (see figure), extending outward, in opposing directions that are substantially parallel to the central axis of the proximal end of the flexible sleeve.

8. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being obvious over Kagan in view of Pierce (U.S. Patent 6,152,956).

With regard to Claim 23, as applied to Claim 3 above, Kagan teaches all the limitations of this claim except that the anchor of the device comprises a non-removable element securely coupled in the hepatopancreatic ampulla or a removable element coupled to the proximal end of

the sleeve, the removable element removably coupled to the non-removable element for removably securing the proximal end of the sleeve in the hepatopancreatic ampulla. Pierce teaches an anchor (82 & 78, Fig. 7A) for a stent within a body lumen comprising a non-removable element (82) securely coupled in the body lumen, and a removable element (78) coupled to the proximal end of the sleeve (44), the removable element removably coupled to the non-removable element (via hooks 86) for removably securing the proximal end of the sleeve. It is also noted by the examiner that it takes only routine skills in the art to modify a stent used in a blood vessel (as taught by Pierce) for in the hepatopancreatic ampulla since both are tubular luminal bodies. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kagan with Pierce so that the anchor comprises a non-removable element and a removable element coupled to the proximal end of the sleeve for the purpose of replacing the sleeve with greater ease. After the modification, the anchor will have its non-removable element securely coupled in the hepatopancreatic ampulla.

With regard to Claim 24, as applied to Claim 23 above, Pierce also teaches that the non-removable element comprises barbs (84) extending from its exterior surface for securing it in the hepatopancreatic ampulla (Col. 7 lines 46-49).

With regard to Claim 25, as applied to Claim 23, Pierce also teaches that the non-removable element (82) comprises a feature (86) adapted for coupling the removable element (78).

With regard to Claim 26, as applied to Claim 1, Kagan teaches the limitations of this claim except that the anchor comprises an annular element having retractable staples. Pierce teaches an anchor (96, Fig. 8) comprises an annular element (see figure) having retractable staples (92), the staples coupled to bodily tissue, when engaged (Col. 8 lines 32-36).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Knudson et al. (U.S. PGPub 2006/0106332) teaches a pancreatic secretion diverter that comprises a tube that couples to the ostium of the hepatopancreatic ampulla and extends into the distal intestine.

McKenna et al. (U.S. Patent 7,314,489) teaches a tube that has its proximal end positioned inside the hepatopancreatic ampulla for diverting digestive enzymes to the distal intestine.

Reydel (WO 2006/088578 A1) teaches a catheter comprising external barbs at the proximal end for engaging with the intermural mucosa of bodily structures such as the hepatopancreatic ampulla.

Briquet et al. (U.S. Patent 6,406,792) teaches biocompatible coatings for medical devices.

Reich et al. (U.S. Patent 5,962,620) teaches the use of polyurethanes in medical devices.

Stack et al. (U.S. Patent 6,675,809) teaches a flexible implanted inside the small intestine from just below the ampulla of vader to the distal intestine for reducing food absorption in the jejunum.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

Art Unit: 4193

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Taghi Arani can be reached on 571-272-3787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. S./
Examiner, Art Unit 4193

/Taghi T. Arani/
Supervisory Patent Examiner, Art Unit 4193
4/24/2008